

### **Remarks**

Please note that the Attorney Docket Number for this application has changed. The new docket number is PF317C1.

Applicants thank the Examiner for the opportunity to discuss the instant restriction requirement during a telephone interview on November 10, 2003. In particular, Applicants asked the Examiner to consider examining at least the polynucleotide claims of Groups I(a) through I(f) as a single group. However, no agreement was reached. Applicants then called the Examiner's supervisor, Gary Kunz, to discuss the issue and to possibly arrange a further interview. Following a brief discussion, Examiner Kunz agreed that the restriction of claims directed to polynucleotides encoding the full-length protein, full-length protein minus the initial amino acid residue, and mature protein into separate groups was atypical of current Patent Office practice. In lieu of another interview, Examiner Kunz indicated that he would discuss the issue with Examiner Romeo directly. He further suggested that in the meantime Applicants should respond to the instant restriction requirement with traverse.

Applicants have herein canceled claims 1-9, 11, and 13-15 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter encompassed by all canceled claims in one or more divisional or continuation applications. New claims 16-75 have been added herein to expand the embodiments of the elected subject matter.

Support for new claims 16-75 can be found in the specification and original claims. In particular, support can be found, for example, at page 7, lines 17-26; page 11, first paragraph; page 15, line 26 through page 16, line 18; and page 20, line 18 through page 26, line 25. Thus, no new matter has been added.

Upon entry of the present amendments, claims 10, 12, and 16-75 will be pending.

### **Provisional Election With Traverse**

The Examiner has required an election under 35 U.S.C. § 121 of one of Groups I-III (Paper No. 20031020, mailed October 23, 2003). The Examiner contends that the inventions or groups of inventions are distinct, each from the other. Page 2, line 1 through page 3, line 9. The Examiner has further restricted the claims into subgroups I(a) through I(f); subgroups II(a) through II(s); and subgroups; II(a) through III(c), based on species of the disclosed CAPP polynucleotide and polypeptide sequences. Page 3, line 11 through

page 7, line 5. The Examiner contends that the subgroups set forth are distinct, each from the other. Finally, the Examiner has also required an election of species. Page 7, line 7 though page 8, line 4.

In response to the restriction requirement, Applicants provisionally elect, *with traverse*, the invention of Group I, represented by originally filed claims 1-9 and 13, and new claims 16-75, drawn to isolated nucleic acid molecules, for further prosecution. In addition, Applicants further elect, *with traverse*, subgroup I(c), directed to polynucleotides having a nucleotide sequence at least 95% identical to a nucleotide sequence comprising amino acids 1 to 365 of SEQ ID NO:2.

In response to the species election requirement, Applicants elect, *with traverse*, polynucleotides encoding amino acids 1 to 365 of SEQ ID NO:2 for further examination. New independent claims 16, 33, 46(c) and 61(c), and dependent claims 17, 22-32, 35-45, 49-60 and 64-75 read on the elected species.

Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the restriction requirement be made final.

#### The Restriction Requirement

With respect to the Examiner's division of the invention into three groups encompassing 28 subgroups, and the reasons stated therefor, Applicants respectfully disagree and traverse.

Applicants point out that even where patentably distinct inventions appear in a single application, restriction remains improper unless the Examiner can show that the search and examination of these groups would entail a "serious burden". *See* M.P.E.P. § 803. In the present situation, the Examiner has failed to make such a showing.

Applicants submit that a search of polynucleotide claims of the invention would also provide useful information for examining claims directed to polypeptides and antibodies of the invention. Therefore, since a search of the claims of Group I would overlap with a search of Groups II and III, a search encompassing the subject matter of Groups I, II and III together would not impose a serious burden.

With respect to the further restriction of claims into subgroups based on species, the Examiner has taken the position that polynucleotides encoding the full-length protein, full-length protein minus the N-terminal amino acid, the mature protein, and substitution

variants of defined scope, are distinct because “following pairwise combinations . . . neither member of a pair is required for the production or use of the other”; and “each of the pair can be manufactured independently of the other”. Paper No. 20031020 at page 4, lines 8-11. Claims directed to polypeptides and antibodies have likewise been restricted into subgroups corresponding to species of the invention. *Id.*, pages 4-7. The Examiner alleges that, with respect to the subgroups, “the searches required are not coextensive.” *Id.*, Page 7, lines 1-2.

Applicants respectfully submit that properly designed sequence searches reveal information relevant not only to the exact query sequence (e.g. nucleic acid sequence encoding the full-length protein), but also to closely related sequences (e.g., nucleic acid sequence encoding the full-length protein minus the initial amino acid residue; the mature protein; or substitution variants of defined scope). It is worth noting that several of the subgroups are substantially overlapping, differing by as little as a single amino acid. Such highly related sequences would clearly be identified by a single, properly designed search. Furthermore, such a search would not entail a “serious burden”, as evidenced by the fact that the Office routinely examines claims directed to nucleic acid or amino acid sequences, or corresponding antibodies, together as a single group, including genus and species claims.

As merely one example of this policy, Applicants point out that in parent application 09/049,022 (now abandoned), the same Examiner of the instant application restricted the exact same claims into only 3 groups, corresponding to polynucleotides, polypeptides, and antibodies. Upon election, polynucleotide claims were examined, presumably including a prior art search, as a single group encompassing nucleic acid molecules encoding the full-length, full-length minus the initial residue, and mature sequences; as well as nucleic acid molecules at least 95% identical to such sequences. The Examiner has provided no reasoning to explain why the burden of examination has changed in the instant application. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement as it pertains to individual species. In particular, Applicants respectfully request that the claims of Group I, including subgroups I(a) through I(f), be examined together.

### The Species Election Requirement

Applicants respectfully submit that the requirement to elect a species is improper in the instant application. Applicants again note that in parent application 09/049,022, the same Examiner examined the polynucleotide claims together as a single group without requiring a species election. The Examiner has provided no explanation for requiring an election of species in the instant application, particularly in view of the restriction requirement dividing the claims into species-based subgroups. Applicants point out that the elected species (polynucleotides encoding amino acids 1 to 265 of SEQ ID NO:2 ) corresponds to Group I(c) set forth in the restriction requirement. It is important to note that there are practical distinctions between a restriction requirement under 37 C.F.R. § 1.142, which divides the application into separately patentable inventions; and a species election requirement under 37 U.S.C. § 1.146, which is done to facilitate searching, and leaves open the possibility of rejoining claims should a generic claim be found allowable. The issuance of a species election in addition to the extensive restriction requirement in the instant application leaves Applicants unclear as to which, if any, claims beyond the elected species will be examined in the instant application; and raises the question whether each species of the instant invention must be prosecuted in a separate application.

Furthermore, although the Examiner has designated claim 3 as generic, that claim is dependent upon, and therefore incorporates the limitations of, claim 1. Applicants respectfully submit that claim 1 is therefore a more appropriate generic claim, as it would read on the polynucleotides of claim 3.

Finally, M.P.E.P. § 809.02(a) states that a proper requirement for election of species should “[c]learly identify each (or in aggravated cases at least exemplary ones) of the disclosed species, *to which claims are restricted.*” *Id.*, at page 800-49; emphasis in original. In the instant species election requirement, the species are not designated. The requirement merely states that “[t]his application contains claims directed to the following patentably distinct species of the claimed invention: each of the species in claim.” Page 7, lines 7-8 (emphasis added). Therefore, it is not clear to which species the Examiner is referring.

Applicants retain the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

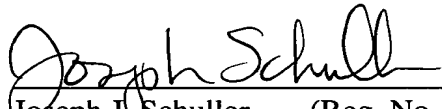
### ***Conclusion***

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: Nov. 21, 2003

  
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